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TITLE: The Effects of Supportive and Nonsupportive Behaviors on
the Quality of Life of Prostate Cancer Patients and Their
Spouses

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INTRODUCTION

Research on prostate cancer has not, as yet, identified how patients' and their spouses' supportive (e.g., giving advice/emotional support) and nonsupportive behavior (e.g., criticizing/avoiding partner) affect and are affected by their: 1) feelings of disease uncertainty, 2) psychological well-being, 3) perceptions of control, and 4) quality of life (QOL). This two year prospective observational survey study explores these issues among approximately 150 early stage prostate cancer patients and their spouses. Specifically, early stage prostate cancer patients and their spouses are asked to complete a questionnaire packet before surgery (radical prostatectomy), and at one, six and twelve months post-surgery. The questionnaire packet assesses perceptions of disease uncertainty, supportive and unsupportive behaviors, perceptions of control, marital satisfaction, and quality of life. The specific predictions to be tested in the study are:

- H1:** Greater levels of illness uncertainty among prostate cancer patients and their spouses will predict significantly lower levels of perceived control.
- H2:** Patient and spouses with low levels of uncertainty and/or high perceived control will need primarily informational and social and instrumental support; individuals with high levels of illness uncertainty and/or low perceived control will need emotional, network and esteem support.
- H3:** Greater illness uncertainty and perceived inadequacies in social support, especially in areas most needed, will correlate positively with frequency and types of non-supportive behaviors.
- H4:** Social support and non-supportive behaviors will mediate the relationship between illness uncertainty and QOL, and between illness uncertainty and psychological well being.
- H5:** Higher levels of uncertainty and lower perceived control will predict poorer QOL, especially shortly after surgery.
- H6:** Spouses will experience poorer QOL than patients.

BODY

During year two of the grant, we have continued to successfully achieve many of our objectives as provided in our statement of work.

Task 1: Plan and develop a tracking system with the Duke Department of Urology to recruit study participants.

Progress

Completed in year one as per the 1999 annual report.

Task 2: Develop and test study questionnaire with 10 prostate cancer patients and their spouses.

Progress

Completed in year one as per the 1999 annual report.

Task 3: Mail out study questionnaires to 150 prostate cancer patients and their spouses along with reminder notices and phone calls (months 3-27).

Progress

In accordance with the letter dated July 26, 2000, from Linda J. Mandeville, a modification to the grant was approved allowing us to continue work as part of a one-year no-cost extension until February 28, 2002. The purpose of the one-year no-cost extension was, in part, due to not yet reaching our study recruitment goal of 150 patients and spouses. As a result of the extension, we began a second recruitment wave in June 2000, which lasted until November 2000. All data collection will end in November 2001.

Results at the end of both recruitment periods were as follows: we were able to recruit close to **83%** of eligible, newly-diagnosed, early-stage prostate cancer patients from the Duke Urology Clinic. As of February 15th 2001, a total of **318** patients were tracked through Duke's Urology Clinic. Of these **318** patients: **186** are currently enrolled in the study, **19** gave verbal agreement but never sent back their questionnaire after all reasonable efforts were made, **20** refused to participate, and **93** were ineligible (**67** chose treatment other than surgery, **11** had a diagnoses of another cancer within less than five years, **4** due to extenuating circumstances (i.e. surgical complications), **4** were mentally incompetent, **2** had recurrent prostate cancer, **2** had been diagnosed more than one yr. ago, **2** were prisoners, and **1** patient was too advanced after clinical exam).

We chose to enroll patients that do not have a spouse or partner. These **17** patients were sent questionnaires without questions that assessed relationship constructs (e.g. social support, marital satisfaction). In addition, on a few occasions we were unable to recruit patients before they had their surgery, as per protocol. However, due to their interest in participating, **7** patients were enrolled at the one-month post-surgery follow-up.

Along with the **186** patients that are currently enrolled in the study, **166** of their partners (spouses or significant others) have completed questionnaires and are enrolled in the study. Table 1 summarizes the current enrollment data:

Table 1: Recruitment Summary as of February 15, 2001

Questionnaire Time point (1)	Total Sent	Total Received	Patients with a Partner (2)	Patients with out a Partner (3)	Partners (4)	Matched Pairs (Dyads) (5)
Baseline						
1 st	320	285	138	15	132	130
2 nd	60	50	24	2	24	24
Total	380	335	162	17	156	154
One month Follow-up (6)						
1 st	232	212	103	8	101	100
2 nd	41	41	20	1	20	20
Total	273	253	123	9	121	120
Six Month Follow-up						
1 st	229	205	98	10	97	96
2 nd	8	8	4	0	4	4
Total	237	213	102	10	101	100
Twelve Month Follow-up						
1 st	226	203	99	10	94	95
2 nd	0	0	0	0	0	0
Total	226	203	99	10	94	95

- 1) The enrollment data is separated by recruitment period. 1st relates to the recruitment period between September 1998 and November 1999, 2nd refers to the recruitment period between June 2000 and November 2000. Total is the sum of the two.
- 2) This column represents the number of patients who **have** a partner (spouse or significant other).
- 3) This column represents the number of patients who **do not have** a partner (spouse or significant other).
- 4) This column represents the number of partners (spouses or significant others) that completed the questionnaires.
- 5) This column represents the number or couples (patients and their spouses or significant others) that completed the questionnaires.
- 6) Some patients who completed baseline questionnaires were lost at follow-up for various reasons. **33** patients were lost because their post surgical pathology report indicated advanced disease, **9** changed their treatment choice, and **1** was lost due to refusal. Thus, **136** patients remained eligible for the one-month follow-up as compared with **179** patients that were enrolled at Baseline. Of these **136** eligible patients **131** completed the one-month follow-up. The total number of **138** completed one-month follow-up patient questionnaires includes the 7 patients enrolled at the one-month time-point.

*** Task 4:** Conduct analyses on baseline data.

Progress

We have now collected all the baseline data to be reported in this study. We have begun baseline data analyses, which will continue into the no cost extension year of the grant.

Tasks 5: Conduct analyses on the one-month data.

Progress

We have now collected all one-month data to be reported. We have begun data analyses of the one-month questionnaire, which will continue into the no cost extension year for the grant.

Tasks 6-8: Conduct Analyses of the six and twelve month post-surgical data and write-up overall project paper(s).

Progress

Data collection will be complete as of November 2001. We will analyze data for the six and twelve month questionnaires as they become complete and will begin write-up of overall project paper(s) when all data has been analyzed.

KEY RESEARCH ACCOMPLISHMENTS

- Initiated and implemented a very successful recruitment procedure which has resulted in reaching approximately **83%** of all eligible early stage prostate cancer patients (A & B) who visit the Duke Medical Center's urology clinic.
- Developed and distributed to patients and their spouses the baseline, and one, six, and twelve month post-surgery questionnaires.
- Have achieved a very satisfactory return rate from patients and spouses, a total of **88%** of baselines mailed were returned. Among the patients, **92%** of the one-month post surgery follow-ups, **90%** of the six-month post-surgery follow-ups, and **91%** of the twelve-month post-surgery follow-up have been completed thus far. The high return rate was similar among the spouses; **93%** of the one-month post surgery follow-ups, **90%** of the six-month post-surgery follow-ups, and **89%** of the twelve-month post-surgery follow-up have been completed thus far.

REPORTABLE OUTCOMES

We have begun preliminary analyses of all baseline and one-month follow-up data. Some of the Key findings are reported below.

- Overall, the quality of life of the patient is substantially poorer than the partner at the one-month post-surgery follow-up than at pre-surgery. The only exception is emotional well-being.
- In general, patients' perceptions of spouses' avoidant and critical behaviors are most strongly negatively related to two quality of life domains at baseline and at the one-month follow-up, emotional well-being and social functioning.
- Spouses baseline perceptions of the patients' avoidant and critical behaviors are unrelated to patients' quality of life one-month post-surgery.
- Baseline patient perceived disease uncertainty is negatively related to all baseline domains of patient quality of life. Furthermore, patient perceived disease uncertainty at baseline is highly negatively correlated, with the exception of role limitations, with all dimensions of quality life at the one-month follow-up.
- Spousal perceived uncertainty at baseline is weakly related to patient quality of life at the one-month follow-up, with the exception of emotional well-being.

CONCLUSIONS

We will continue to analyze the baseline and one month data incorporating the new cohort of patients and spouses, and anticipate data collection to end November, 2001. We envision a paper to be submitted on some preliminary findings during November or December of 2001.

REFERENCES

Not applicable at this time.

APPENDICES

Not applicable at this time.